REMARKS

The above amendments to the above-captioned application along with the following remarks are being submitted as a full and complete response to the Office Action dated March 18, 2003. In view of the above amendments and the following remarks, the Examiner is respectfully requested to give due reconsideration to this application, to indicate the allowability of the claims, and to pass this case to issue.

Claims 1-18 are currently pending in this application. Claims 1, 11 and 18 are being amended, as set forth above and in the attached marked-up presentation of the claim amendments, in order to more particularly define and distinctly claim applicants' invention. Further, the specification is being amended to correct an error which was inconsistent with other portions of the specification. Applicants hereby submit that no new matter is being introduced into the application through the submission of this response.

Formality Rejection

Claim 11 was objected to for a typographical error, and claims 1-13 and 18 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite As indicated, the claims have been amended as required by the Examiner. Accordingly, the withdrawal of the outstanding informality rejection is in order, and is therefore respectfully solicited.

Prior Art Rejections

Under 35 U.S.C. § 102(b), Claims 1, 2, 5 and 11 were rejected as being anticipated by U.S. Patent No. 5,153,319 to Crauthers et al. (hereinafter "Crauthers"), and Claims 14, 15, and 17-18 were rejected as being anticipated by U.S. Patent No. 5,910,423 to Yamazaki et al (hereinafter "Yamazaki").

Under 35 U.S.C. § 103(a), Claims 6 and 7 were rejected as being unpatentable over Crauthers, Claims 3, 4, and 8-10 were rejected over Crauthers in view of U.S. Patent No. 6,368,400 B1 to Baldwin et al. (hereinafter "Baldwin"), Claims 12 and 13 were rejected over Crauthers in view of U.S. Patent No. 6,211,349 B1 to Dale et al (hereinafter "Dale"), and Claim 16 was rejected over Crauthers in view of Baldwin, and further in view of Strategene Catalog

(1988, p. 39). Applicants have reviewed the cited references and hereby respectfully traverse the rejections.

The method for isolating and purifying nucleic acids of the present invention, as now recited in claim 1, comprises: providing a mixed solution containing the nucleic acids, salts, and at least one organic solvent; adsorbing the nucleic acids on an adsorption support; washing the support adsorbed with the nucleic acids with a washing buffer; desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids (page 3, lines 8-14). The organic solvent includes at least one compound containing 2 to 10 carbon atoms selected from the group consisting of aliphatic ether, aliphatic ester, and aliphatic ketone.

The present invention as set forth in claim 14 is directed to a reagents kit for use in isolating and purifying nucleic acids by causing the nucleic acids to be adsorbed on an adsorption support, comprising: a mixed solution containing salts and an organic solvent for enabling adsorption of nucleic acids, a washing buffer, and an elution buffer. The organic solvent comprises at least one compound containing 2 to 10 carbon atoms selected from the group consisting of aliphatic ether, aliphatic ester, and aliphatic ketone.

As defined in the Electrochemistry Dictionary which is available online at http://electrochem.cwru.edu/ed/dict.htm#a28, *adsorption* means adhere or attach molecules or ions to outer surfaces or interfaces so as to increase the concentration of a solute in the vicinity of a solid surface, over that in the bulk of the solution, due to the attractive interaction between the solid immersed into the solution and the solute. The binding to the surface is usually weak and reversible. It is a surface process such that the accumulating molecules do **not** actually penetrate the substance on which they are formed. The term is not to be confused with absorption (filling of pores in a solid). The invention reduces viscosity and promotes defoaming of the obtained nucleic acid-containing solution. The yield of the recovered or collected nucleic acids is increased without incurring move contamination. Additionally, the nucleic acids recovery time is shortened (page 4, lines 17-22).

Applicants contend that none of the cited prior art references teaches or suggests such an adsorption method or reagents kit for isolating and purifying nucleic acids.

In contrast to the present invention, Crauthers describes an intermediate nucleotides **bound** to an inorganic polymer support for the synthesis of polynucleotides (Abstract). The support comprises the inorganic polymer which is **chemically bound** (rather than **"adsorbed"**)

with a nucleotide, e.g., an amide linkage formed by amino group with carboxy group (col.1, line 60 - col.2, line 2). To provide the nucleoside-modified support, the silica gel support is preferably linked to the nucleotide via an ester linkage (preferably). The linkage is provided by first linking carboxy functionality to the support, or by performing the ester linkage on the nucleotide via esterification followed by condensing the esterified nucleotide through the esterifying acid moiety to the support (Col. 4, lines 13-24). As such, the linkage creating process (col. 4, lines 25-57) does **not** utilize a mixed solution containing the nucleic acids, salts, and at least one organic solvent as the invention.

The organic solvent replied upon by the Examiner (Example 5; col. 16, line 43- col. 17 line 37 "***covalently bound***") is used to **chemically bound** nucleotide to the modified support and purify the desirable olidonucleotide, bot not to **adsorb** nucleotide to the support.

Yamazaki makes water soluble powdered formulation. There is no information for absorbing the nucleic acids on an adsorption support or a mixed solution containing salts and an organic solvent for enabling adsorption of nucleic acids in the cited portion.

The other cited references fail to compensate for Crauthers or Yamazaki's deficiencies since none of them teach or suggest an adsorption method or reagents kit for isolating and purifying nucleic acids recited in claims 1 and 14.

Baldwin uses an absorbing ether-like compound, which is attached to a naphthalene or anthracene chromophore via an oxygen linkage, for absorbing organic light in anti-reflective layers in photolithography (Abstract, Col. I, lines 6-11). The teachings in Baldwin are not within the field of Applicants' endeavor and are not reasonably pertinent to the particular problem of isolating and purifying nucleic acids by eluting nucleic acids from nucleic acid-containing samples (lines 6-8, page 1) with which Applicants is concerned.

In addition, contrary to the Examiner's allegation that it's obvious for one skilled in the art to combine Baldwin and Crauthers, they are not analogous art. The field of Baldwin, i.e., the compound for photolithography, is different Crauthers, i.e., intermediate nucleotides bound to an inorganic polymer support. It has not been shown that a person of ordinary skill, seeking new intermediate nucleotides bound to an inorganic polymer support, would reasonably be expected or motivated to look to the teachings of absorbing ether-like compound in Baldwin. In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992); M.P.E.P. 2100-105.

Dale prepares and uses nuclease resistant and acid resistant protonated/acidified nucleic acids to treat or prevent a bacterial infection (Abstract), it describes a standard method to purify the antibacterial nucleic acids by chromatography on reverse phase media or ion exchange media (Col. 10, lines 40-56). However, there is no information regarding the contents of the solution for the purification.

In addition, contrary to the Examiner's allegation that it's obvious for one skilled in the art to combine Dale and Crauthers, they are not analogous art. The field of Dale, i.e., preparing and using nuclease resistant and acid resistant protonated/acidified nucleic acids to treat or prevent a bacterial infection, is different from that of Crauthers, i.e., intermediate nucleotides bound to an inorganic polymer support. It has not been shown that a person of ordinary skill, seeking new intermediate nucleotides bound to an inorganic polymer support, would reasonably be expected or motivated to look to the teachings of Dale.

Stratagene Catalogue shows the gene characterization kits that provide the materials to map, sequence, transcribe, cap, hybridize nucleic acid (lines 4-7, page 39), which is not in the same field of the invention (isolating and purifying nucleic acids) or of Crauthers. It has not been shown that a person of ordinary skill seeking to solve the particular problem with which the invention or Crauthers is concerned, would reasonably be expected or motivated to look to the teachings of the Stratagene Catalogue.

The Examiner's reliance upon the "common knowledge and common sense" of one skilled in the art for motivation to combine the teachings did not fulfill the agency's obligation to cite references to support its conclusions. Instead, the Examiner must provide the specific and positively recited teachings of the combinations on the record to allow accountability.

> *To establish a prima facie case of obviousness, the Board must, inter alia, show "some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). "The motivation, suggestion or teaching may come explicitly from statements in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved." Kotzab, 217 F.3d at 1370, 55 USPQ2d at 1317. .... Recently, in In re Lee, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002), we held that the Board's reliance on "common knowledge and*

common sense" did not fulfill the agency's obligation to cite references to support its conclusions. Id. at 1344, 61 USPQ2d at 1434. Instead, the Board must document its reasoning on the record to allow accountability. Id. at 1345, 61 USPQ2d at 1435.

See In re Thrift, 298 F.3d 1357.

Such an obligation to provide specific teaching(s) also applies to all existing or future obviousness rejections.

Consequently, Applicants contend that none of the cited references, by themselves, can anticipate or render obvious each and every feature of the present invention as now claimed. Even more, none of the references provides any disclosure, teaching or suggestion that would make up for the deficiencies in the others nor that would motivate their combination so as to render each and every feature of the invention as claimed obvious to one of skill in the art. Rather, the present invention as a whole as now claimed is distinguishable and thereby allowable over the prior art.

In view of all the above, Applicants respectfully submit that certain clear and distinct differences as discussed exist between the present invention as now claimed and the prior art references upon which the rejections in the Office Action rely. These differences are more than sufficient that the present invention as now claimed would not have been anticipated nor rendered obvious given the prior art. Rather, the present invention as a whole is distinguishable, and thereby allowable over the prior art.

Favorable reconsideration of this application as amended is respectfully solicited. Should there be any outstanding issues requiring discussion that would further the prosecution and

allowance of the above-captioned application, the Examiner is invited to contact the Applicants' undersigned representative at the address and phone number indicated below.

Respectfully submitted,

Stanley P. Fisher
Registration Number 24,344

Juan Carlos A. Marquez
Registration Number 34,072

REED SMITH LLP
3110 Fairview Park Drive
Suite 1400
Falls Church, Virginia 22042
(703) 641-4200
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SPF/JCM/JT

MARKED-UP VERSION OF THE CLAIM AMENDMENTS

1. A method for isolating and purifying nucleic acids, which comprises.

providing a mixed solution containing the nucleic acids, salts, and at least one organic solvent;

[absorbing] adsorbing the nucleic acids on an adsorption support;

washing the support adsorbed with the nucleic acids with a washing buffer;

desorbing the nucleic acids from the support with an elution buffer thereby recovering the nucleic acids, wherein

said organic solvent includes at least one compound containing 2 to 10 carbon atoms selected from the group consisting of aliphatic ether, aliphatic ester, and aliphatic ketone.

11. The method for isolating and purifying nucleic acids as claimed in Claim 1, further comprises:

providing a column with a bottom;

placing the support above the bottom;

causing the mixed solution to pass one-way through the support to the bottom by a sucking force.

18. The reagents kit as claimed in Claim 14, wherein the organic solvent comprises at least one of aliphatic ether, aliphatic ester, aliphatic ketone.